

AIR RESOURCES BOARD

AIR QUALITY ADVISORY COMMITTEE MEETING

APRIL 3, 2002

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
1515 CLAY STREET, ROOM 2, SECOND FLOOR
OAKLAND, CALIFORNIA

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APPEARANCES:

For the Air Quality Advisory Committee:

Michael Kleinman, Ph.D., Chairman, UC-Irvine

Russell Sherwin, M.D., UCSF

Constantinos Sioutas, D.Sc., Associate Professor, USC

Michael P. Sherman, M.D., Professor, UC-Davis

Dean Sheppard, M.D., Professor, UCSF

Ira B. Tager, M.D., M.P.H., Professor, UC-Berkeley

Gerry Cropp, M.D., Ph.D., Professor Emeritus, UCSF

Henry Gong, M.D.

Also Present:

Richard Bode, Chief, Air Resources Board, Health Exposure
and Assessment Branch

Bart Ostro, Ph.D., Office of Environmental Health Hazard
Assessment

Michael Lipsett, M.D., J.D., Office of Environmental Health
Hazard Assessment

Members of the Public:

John Heuss, Air Improvement Resources, Inc., on behalf of
American Alliance of Automobile Manufacturers

David Schonbrunn, President, Transtaff

Diane Bailey, Natural Resources Defense Council

Ken Kloc, Environmental Law and Justice Clinic, Golden
Gate University School of Law, on behalf of Our Children's
Earth Foundation

Bonnie Holms-Gen, American Lung Association and American
Lung Association of California

INDEX

	Page
Introductions and Staff Overview	4
Chief Richard Bode	4
Staff Presentation of PM2.5 Proposal	7
Dr. Michael Lipsett	7
Oral Public Comments	16
John Heuss	16
David Schonbrunn	21
Diane Bailey	23
Ken Kloc	25
Bonnie Holmes-Gen	29
Summary of Written Comments	32
Dr. Bart Ostro	32
Questions and Comments	39
Conclusion and Wrap-up	49
Adjournment	57
Certificate of Reporter	58

1 P R O C E E D I N G S

2 CHIEF BODE: Good morning. I'm Richard Bode with
3 the Air Resources Board, and I want to welcome you to the
4 second Air Quality Advisory Committee meeting to review the
5 particulate matter standards for the California ambient air
6 quality standards.

7 First off, I'd like to thank the AQAC for actually
8 lending us their time after we -- we had a meeting in
9 January in which we reviewed the initial proposal. That
10 proposal came out on November 30th, 2001. And I'm really
11 amazed, at that meeting we had the committee review the
12 document and one of their strongest recommendations was they
13 wanted to see the staff come back with a proposal for a 24-
14 hour PM2.5. And that is really the primary focus of today's
15 meeting here.

16 So I first want to start off and thank the
17 committee members for really giving us their time for a
18 second meeting so quickly after the first that I'm really
19 amazed we got all these people together here.

20 I'm quickly going to go through the agenda, and
21 hopefully everyone got a copy of the agenda -- if not, it's
22 on the front table right there -- and I'll tell you first
23 that I am going to take a very quick amount of time here and
24 do a quick overview, and have the rest of the time here
25 spent on the actual proposal presentation, which will be

1 done by Dr. Michael Lipsett from the Office of Environmental
2 Health Hazard Assessment.

3 Following that there will be an oral public review
4 comment period, and I've been asked by Dr. Kleinman too that
5 anyone who is interested to please sign up at the front
6 table over here, that we have a certain amount of time set
7 aside and we want to make sure that we have adequate time
8 for everyone. So if you are going to make a public
9 statement, please sign up for that and we'll hand that to
10 Dr. Kleinman during the staff presentation here so he can
11 identify how much time each person can have.

12 Another thing to keep you aware too is that the
13 real purpose of this meeting is to look at the PM2.5 24-hour
14 proposal that staff has put out, and so comments really
15 should be focused on that proposal itself. Following that
16 comment period, according to our agenda too, we'll have the
17 staff of ARB and OEHHA and especially OEHHA will then
18 respond to some of the written comments that we've received
19 so far. And finally, we'll let the committee actually do
20 its review of the proposal.

21 Let me point out, and I'd mentioned this already,
22 that the real focus of today's meeting is the proposal that
23 was put out on March 12th to establish a new PM2.5 24-hour
24 standard that the reason we're bringing this forward too is
25 at the request of the committee, the Air Quality Advisory

1 Committee, through their comments that they had given us at
2 their January 23rd meeting.

3 And, just to kind of go over the process itself,
4 what's going to follow after this too is that the committee
5 itself, through Dr. Kleinman, will then put their findings
6 together, based on comments at both of the two meetings, the
7 January and the April meeting, put those into final
8 findings, that staff will respond to those comments and
9 findings and modify our staff report and proposal, in
10 accordance with those findings.

11 In May, early May we will put out a final draft
12 staff report with our final recommendations, and that opens
13 up a new 45-day public comment period that during that same
14 May period we'll again have probably public workshops, we'll
15 go out to the public to explain any changes in our
16 recommendation based on the AQAC review. And finally, we
17 will take the staff recommendations to the Air Resources
18 Board meeting on June 20th, 2002.

19 Just to kind of remind you, this is a change in
20 the schedule we brought to you in January, that based on
21 putting together, developing this additional proposal for
22 the PM2.5 24-hour standard, we've really pushed everything
23 off for a month. And actually, it's pretty amazing that
24 OEHHA and AQAC and ourselves could get together and put all
25 this together and still meet a monthly time period here to

1 get together in June.

2 So with that, I think I'm done with my
3 introductions, and I'm going to introduce Dr. Michael
4 Lipsett and I'll let you go from there.

5 DR. LIPSETT: All right. Well, thank you,
6 Richard. Well, as you can see, Richard and I coordinated
7 our talks ahead of time. There's a little bit of redundancy
8 here initially.

9 But basically, last January the committee
10 generally supported our description of the scientific
11 foundation for the air quality standards recommendations,
12 and more or less concurred that the standards that we
13 recommended were supported by scientific evidence. However,
14 the committee unanimously did not agree with our decision to
15 not develop a 24-hour PM2.5 standard and, in the draft
16 findings that Dr. Kleinman forwarded to us, said that
17 basically the committee has strongly indicated that the
18 major shortcoming of the previous recommendations was the
19 lack of development of a 24-hour PM2.5 standard.

20 So taking our guidance from the committee, we went
21 back and looked at the evidence again, and there certainly
22 is substantial evidence in the published literature that
23 would lead one to think there is a need for a 24-hour 2.5
24 standard, and in particular, in the various time series and
25 panel studies, 24-hour PM2.5 averages in a number of

1 locations throughout the world have been associated with a
2 variety of adverse outcomes, including increased daily
3 mortality.

4 We know that PM2.5 deposits and is retained as
5 substantial quantities in the airways and within the deep
6 lung and in the interstitium. And, you know, unlike coarse
7 particles -- I shouldn't say unlike coarse particles, but
8 there is substantial penetration into residences, so that
9 people can be continuously exposed to ambient concentrations
10 of PM2.5. There have been several controlled exposure
11 studies to diesel and concentrated airborne particles that,
12 even though these levels are substantially higher than what
13 one sees in ambient exposures, like around 200-300
14 micrograms per cubic meter, that these are associated with
15 inflammatory effects.

16 And there have been a number of studies that
17 suggest potential mechanisms that might link exposure to
18 ambient PM2.5 with cardiovascular outcomes; in particular,
19 decreased heartrate variability, increased risk of serious
20 arrhythmias among people with implantable defibrillators,
21 and increased risk of myocardial infarction.

22 In addition, we recommended last time that we have
23 an annual average in California of 12 micrograms per cubic
24 meter. This would shift the whole distribution of PM2.5
25 from where it currently is, it would shift it downward,

1 including both mean and peak concentrations. Nonetheless,
2 the ARB went through a modeling exercise for us, looking at
3 expected peak daily concentrations that would be expected in
4 a variety of areas of California that, even if they were in
5 attainment with this new annual average, would indicate that
6 the peak concentrations would still be in ranges that could
7 be harmful, up in the range of 40 micrograms per cubic meter
8 and above.

9 So -- Well, I guess I trademarked that last line
10 there. The computer reads it differently from what's on the
11 disk there, but this is supposed to be an arrow that implies
12 a suggested need for a short-term standard. Okay, so that's
13 in areas that might otherwise be in attainment with the
14 annual average, that you could still see peak concentrations
15 that would be in an area that we'd be concerned about.

16 Okay. So what do we do at that point? Well,
17 first, we took a couple of California data sets that we had
18 available, looking at PM2.5 and mortality. Our Coachella
19 Valley data set and then the one in Santa Clara Valley,
20 which David Fairley of the Bay Area Air District helped or
21 did some analysis on, and while it may seem like we were
22 reinventing the wheel a bit, what we wanted to do was to see
23 if we could identify any evidence for non-linearity or a
24 threshold in these exposure response relationships.

25 So we used a variety of different methods,

1 piecewise linear aggression, using a bunch of different
2 "hockey-stick"-type functions. Used general additive
3 models, using locally weighted smooths. Trimming analysis,
4 where we basically sequentially lopped off the highest
5 levels of PM2.5 down to lower levels, and Bayesian models,
6 examining the likelihood of thresholds at different PM2.5
7 concentrations. And basically we came up with the same
8 result, that others looking at larger data sets, multi-city
9 data sets came up with, which is that the data could be best
10 described by this linear non-threshold model, that none of
11 the other models fit the data any better.

12 So what does this mean? It implies, as we said at
13 the last meeting, that there is no bright line, no obvious
14 place to draw the line for a 24-hour standard. You know,
15 one of the things we did observe, however, was that as you
16 got lower levels of PM2.5 that there was greater uncertainty
17 with respect to the estimates, in terms of the confidence
18 intervals being consistent with there being no increase in
19 risk.

20 And we have this additional issue that we have to
21 be concerned with in setting standards in that the enabling
22 legislation says that ambient standards are to be
23 established at levels that adequately protect the health of
24 the public, including infants and children, with an adequate
25 margin of safety. So without this bright line, it makes

1 this last part a little bit challenging, but I'll get to how
2 we address this momentarily.

3 First, as with the PM10 standards, what we decided
4 to do was base the standard on those studies that linked
5 PM2.5 with mortality, but why is this, and that -- it's the
6 same explanation, is that morbidity and mortality outcomes
7 appear to occur within the same PM2.5 concentration ranges.
8 So when folks, you know, mortality, the underlying
9 assumption is that a standard that is adequate to protect
10 against increases in mortality should also protect against,
11 specifically against increases in a variety of morbidity
12 outcomes as well.

13 So taking our cue from one of the suggestions that
14 the Air Quality Advisory Committee made -- I think it was
15 Dr. Sheppard, in fact I'm sure it was Dr. Sheppard -- we
16 identified indicators of PM2.5 distribution, and focusing on
17 the means and the upper tail of the distribution. We used
18 the 98th percentile of these distributions, rather than the
19 extremes because that's somewhat more stable, it's somewhat
20 less subject to the meteorologic vagaries that determine
21 what happens at the very extremes of the distribution.

22 And so what we're recommending is that this
23 distribution in California be reduced below the levels of
24 the distributions and studies that robustly link PM2.5 and
25 increases in daily mortality. And, in addition, we're

1 incorporating this additional margin of safety in the form
2 of a standard, a not-to-be-exceeded standard. This is a
3 form that the Air Resources Board has consistently used for,
4 well, since time immemorial, and rather than taking the
5 approach that US EPA does of using the 98th percentile.

6 So, again, we're left shifting the PM2.5
7 California distribution so that the mean and peak
8 concentrations are below those in which effects have been
9 observed. So the annual standard of 12 is placed below the
10 long-term means of these published studies that link PM2.5
11 with increased daily mortality. And so we want the 24-hour
12 standard to be below the upper tail of the 98th percentile
13 of these distributions.

14 So we obtained data on the means, these were
15 mainly published, and then the upper 98th percentiles which
16 we had to contact the authors of these papers for, for
17 the -- I guess it was about a little more than a dozen
18 published papers looking at low levels of PM2.5 and daily
19 mortality. And for these studies that did identify the
20 strong associations, the long-term means ranged from 13 to
21 21 micrograms per cubic meter, which the 98th percentiles
22 ranged from 30 to 51. And again, we did see greater
23 uncertainty of effect at lower ambient levels.

24 And why would you see this greater uncertainty?
25 Well, I mean, it's very likely due to decreased statistical

1 power. There are fewer health impacts expected at these
2 lower concentrations. The issues of exposure measurement
3 error are -- while they are always important in air
4 pollution epidemiology, they may have a greater impact here.
5 And issues of compounding by co-pollutants or weather
6 factors and possibly by differences in particle mixtures as
7 well.

8 So finally, we ended up choosing the 25 micrograms
9 per cubic meter. We started with the 30, which is at the
10 95th percentile in the Vancouver study. In the Vancouver
11 study the long-term mean was 13. This 30 is also consistent
12 with a PM2.5/PM10 ratio of about .6. If you look at the
13 PM10 24-hour standard of 50, this ratio overall is somewhat
14 high. When you look at the distribution of these
15 concentrations within California, the range goes from about
16 .11 to .91, with the midpoint somewhere around 50 to 55.

17 And then in light of this legislative directive
18 regarding adequate margin of safety, we suggested a value of
19 25 being somewhat below this. This brings the PM2.5/PM10
20 ratio at the standards level to about exactly .5, and having
21 this not-to-be-exceeded form of the standard basically cuts
22 off the extreme value of the California distribution,
23 assuming this eventually, we come into attainment with this,
24 at a level that is below, like I said, the 98th percentile
25 study that has the lowest 98th percentile, which -- Okay,

1 I'm getting confused here -- the study that showed a strong
2 association, a significant association with the lowest level
3 of 98th percentile.

4 This specification will also ensure that the
5 numbers of days between what would be the mean value, say,
6 of the Vancouver study and of our distribution, that the
7 number of days that occur above these, which are, in all
8 probability, driving a lot of the relationship is what is
9 seen in Vancouver and the other studies, but these are going
10 to be dramatically reduced with this formulation.

11 And, with that, I'd like to end our initial
12 presentation. I don't know if any of the committee members
13 have any questions, but I'd be happy to answer them.

14 DR. CROPP: One question I had was are the ranges
15 that you looked at, 13 to 21 micrograms per cubic meter at
16 which the mortality studies were done, was it reasonable to
17 apply to children where we have a varied level of any
18 mortality, but we still have morbidity?

19 DR. LIPSETT: I think it is reasonable, and,
20 again, there is a substantial -- we don't expect children,
21 at least most children we're not expecting increased risks
22 of mortality. There are some suggestive studies that there
23 may be perinatal mortality associated with excursions of
24 PM2.5, but those are in -- there's relatively little
25 literature on that, and the levels generally tend to be

1 higher than the levels that we're looking at here.

2 And, Bart, did you want to amplify that?

3 DR. OSTRO: No, I think what you said was right,
4 that the two studies that show effects on children regarding
5 mortality have been in Bangkok and Mexico City, where the
6 levels are a lot higher, so the morbidity outcomes appear to
7 occur at the same basic levels in children as the mortality
8 effects seem to be appearing, probably with older people
9 with cardiovascular disease.

10 DR. CROPP: But should we include a statement in
11 that regard in your reasoning for choosing the levels that
12 you did?

13 DR. LIPSETT: You mean a statement specifically
14 related to children's morbidity?

15 DR. CROPP: Yes.

16 DR. LIPSETT: Yeah, we could certainly do that. I
17 think that there is something in there about morbidity
18 generally --

19 DR. CROPP: Yes, right.

20 DR. LIPSETT: -- but if you want us to focus on
21 children, I'm sure we can do that.

22 So I guess now it's -- Richard, were you going
23 to -- or Mike, with respect to public comments?

24 CHAIRMAN KLEINMAN: I believe we had five
25 individuals sign up, Richard?

1 CHIEF BODE: That's correct.

2 CHAIRMAN KLEINMAN: For the public comments, what
3 we would like to do is allow each speaker about five minutes
4 to present a summary. Most of these speakers have also
5 presented written comments, which will be dealt with in a
6 more detailed way. Rather than rehash the entire written
7 comment, just a brief overview of what those comments were,
8 and any new information that should be presented.

9 And we'll just take the speakers in the order that
10 they signed up. So John Heuss?

11 SPEAKER HEUSS: Heuss, yes.

12 I have transparencies, but I can --

13 CHAIRMAN KLEINMAN: John, we have a projector.

14 SPEAKER HEUSS: Okay. While they're setting up,
15 I'll just note that I'm with Air Improvement Resources,
16 Inc., but this afternoon I'm speaking on behalf of the
17 Alliance of Automobile Manufacturers.

18 And we have two main messages. The first message
19 is that we feel the proposed standard is not based on a
20 rigorous analysis of all the relevant factors. It turns out
21 the proposed standard is now substantially more stringent
22 than the proposed annual standard, and that makes it by far
23 the controlling standard. And we question whether that is
24 the intent on the part of AQAC and OEHHA.

25 And our main concern with that is that this

1 proposed standard is comparable to background levels, and in
2 a practical sense will be unachievable in significant
3 portions of California. Instead, we recommend a more
4 sensible interim standard and conducting controlled health
5 effect studies. We recommend controlled health effect
6 studies at low concentrations to try to figure out which are
7 the most toxic of the gases and particles that are still
8 left in your air.

9 And our concern with the health basis, as has been
10 proposed, is that there are no controlled experiments
11 showing effects anywhere near these kinds of concentrations.
12 And the findings from toxicology, dosimetry, and
13 occupational studies, places where we have been exposing
14 large populations to different kinds of particles for long
15 periods of time are not summarizes. Instead, we relied
16 totally on the epidemiology. We presented 20-some pages of
17 detailed review of that material. I'm not going to go
18 through that except to make Dr. Chalk's point that based on
19 his simulations, it's premature to adopt the idea of a
20 linear non-threshold dose response.

21 We're concerned the standard is impractical and
22 unachievable. Twenty-five micrograms per cubic meter as a
23 peak level is comparable to peak background concentrations,
24 and achieving that level would require achieving an annual
25 standard of about eight micrograms per cubic meter. And

1 then that means that it by far is the controlling standard.
2 When EPA reviewed this issue, when they set the federal
3 PM2.5 standards, they specifically chose not to make the 24-
4 hour standard the controlling standard. They rejected a
5 proposal of 20 because it was conflicted by the background.

6 The form of the standard that's been proposed
7 never to be exceeded we think also creates significant
8 problems. It pushes the allowed concentrations down even
9 further. A never-to-be-exceeded form does not allow for the
10 naturally occurring concentration fluctuations and districts
11 would have to somehow plan for this, and it's very difficult
12 to see a never-to-be-exceeded standard fitting into an
13 attainment demonstration, a real plan to achieve it. And
14 essentially, this will drive the PM distribution to overlap
15 with the background distribution.

16 The conclusion we draw is the proposed standard is
17 not scientifically sound and is unachievable, even with
18 complete illumination of fossil fuel combustion in
19 California. I'm speaking on behalf of the automobile
20 manufacturers, and I'd just like to point out that the
21 significant reductions in PM from motor vehicles, cars and
22 diesels that has occurred well over 90-percent fleet-wide
23 for all these occurred without this standard, and with this
24 standard there is still going to be the push to get those
25 emissions to zero as soon as technologically possible. So

1 it's really not that issue that drives our comments.

2 The recommendations we make are that if a standard
3 is deemed necessary that we adopt an interim standard with a
4 more robust statistical form, akin to the 98th percentile
5 that the EPA came up with. Something that is not more
6 controlling than the annual standard and, based on an
7 analysis of what the peak background levels in various areas
8 in California of would be, would be something that would be
9 achievable.

10 On the one hand, we think that's a recommendation
11 that makes sense, but the other part is that controlled
12 health effects studies of both PM and gases and combinations
13 at the ranges that currently occur in California are really
14 important to try to find out which are the most toxic
15 components to work on.

16 I have a couple of other transparencies, if I
17 could have a minute or so. And I guess on the epidemiology,
18 the only one that I would raise here is the issue that
19 single-pollutant models are really inappropriate when the
20 next pollutant comes along and in succeeding years you'll be
21 looking at ozone, CO, NO2, you'll need to address that
22 issue. If people are allowed to use single-pollutant
23 models, when studied by David Fairley who is in the audience
24 today, it can be used to set every standard you have at
25 background. Whether that's realistic or not, whether or not

1 his study is the one study that should drive the world, I
2 don't know. We have in our comments pointed out that his
3 results in San Jose and NMAP's results in San Jose have some
4 similarities, but also some major differences.

5 And the last point is a little more detail about
6 the background. There are natural emissions of gases.
7 There are also natural emissions of particles. There are
8 significant numbers of biological particles, which may be
9 some of the most toxic. There is windblown dust that gets
10 into the fine fraction as PM2.5. There are also a variety
11 of manmade activities which are subject to some control, but
12 there are some parts of that which you won't be able to
13 control, and we think you need to take that uncontrollable
14 PM into consideration.

15 There is no one background. The sources are
16 regional, some are seasonal, some things are episodic. But
17 when you look in detail at the peak-to-mean ratios of PM2.5,
18 they average around three. And if you look at all of the
19 sites in the western US that don't have a large sulfate
20 signal, and you look at the cleanest sites which are below
21 ten micrograms per cubic meter, mean PM2.5, that ratio
22 ranges from two up to ten. And one of the reasons for that
23 is the thing that was in our comments about PM1 is really
24 the cut point where you can keep coarse particles out, and
25 this intermodal PM1 to PM2.5 does include, of course,

1 intrusion, which can be half of the PM2.5 during windblown
2 dust events, as reported by Clayborn, et al., in Spokane.

3 CHIEF BODE: Thank you.

4 CHAIRMAN KLEINMAN: Thank you, Mr. Heuss.

5 David Schonbrunn?

6 SPEAKER SCHONBRUNN: Committee members, I'm David
7 Schonbrunn with Transtaff. We are a Bay Area-based
8 environmental organization that is focused on air quality
9 and transportation. We're currently litigating a series of
10 issues in the Bay Area, trying to overturn EPA's recent
11 lifting of the conformity lapse that the Bay Area has been
12 in.

13 I'm particularly pleased to be able to speak to
14 you after the previous speaker. We urge you to put that
15 information in context and basically ignore it.

16 (Laughter.)

17 SPEAKER SCHONBRUNN: These are the same people
18 that vehemently resisted seat belts, CAFE standards, and
19 basically every other improvement that's been in the public
20 interest. Practicality, which is one of the key pitches
21 that you just heard, is not part of ARB's charge under law
22 in setting these standards. The standards are to be health-
23 protective. So the whole issue of practicality is a red
24 herring.

25 I'd like to ask the last speaker if he'd like to

1 volunteer as an experimental subject for controlled exposure
2 studies. I think what he's asking for is perhaps unethical,
3 and it's certainly hard to imagine who would want to
4 participate in such experiments.

5 We are very pleased with the draft proposal from
6 staff, strongly support it and specifically its do-not-
7 exceed designation. This is a very important public health
8 initiative, and we thank you for your efforts in coming
9 together today and at the last hearing and making this
10 happen.

11 Now, one of the areas that we're particularly
12 interested in is that it appears that the data could support
13 an even lower 24-hour standard, given the requirement to
14 protect public health with an adequate margin of safety.
15 Dr. Sheppard's proposed methodology used a ten-microgram-
16 per-cubic-meter exceedence over the health effects level.

17 Now, the point that I think is important to
18 mention is that that idea, which is compatible with the
19 current staff proposal, was essentially arbitrary, the ten
20 microgram per cubic meter was arbitrary. And, in fact, a
21 lower threshold or rather a lower number could actually be
22 appropriate. So in our view, this proposal represents an
23 upper limit as opposed to a lower limit for a standard.

24 Given the previous speaker, we know there will be
25 great pressure on ARB to compromise our health standards and

1 go for a more lax standard. So on that basis, we ask you to
2 support the staff recommendation and add the following two
3 points: The first is to ask ARB to maintain an ongoing
4 review of the literature and to initiate a new process when
5 new data supports a stronger, more health-protective
6 standard, especially for children. It's apparent that this
7 standard is not as focused on children as I believe the
8 legislation calls for. So making the current proposal
9 become our state standard would be a huge step forward, and
10 future steps forward may be appropriate as the literature
11 develops.

12 And my second comment was to ask you to make a
13 specific finding that a numerically higher 24-hour standard
14 or one without a not-to-exceed characteristic would clearly
15 be injurious to the public health. It's my belief that if
16 you were to make such a finding that that would carry a
17 great deal of weight and would be very helpful in the
18 contentious proceedings that will be occurring later.

19 Thank you very much.

20 CHAIRMAN KLEINMAN: Thank you.

21 Diane Bailey?

22 SPEAKER BAILEY: Good afternoon, members of the
23 committee. I thank you for this opportunity to speak here
24 today. Again, my name is Diane Bailey and I am a scientist
25 with the Natural Resources Defense Council, and I'll keep my

1 comments very brief here.

2 NRDC strongly supports the establishment of a 24-
3 hour standard for PM2.5 as it was set forth in the ARB and
4 OEHHA's draft proposal on March 12th. At the same time we
5 would like to caution the committee that the proposed
6 standard is the weakest that is scientifically defensible,
7 given our current knowledge of the health effects of fine
8 particulates.

9 We urge this committee, as well as the agencies,
10 to preserve the proposed 24-hour PM2.5 standard of 25
11 micrograms per meter, cubed. And also, we urge you to
12 resist any pressure to relax the standard, as it is an
13 essential addition to the proposed new particulate standards
14 as a whole. We believe that both the short- and long-term
15 standards for fine and coarse particulates are necessary to
16 protect public health with an adequate margin of safety.
17 And this is something that's required by the law.

18 Numerous studies have shown human health effects
19 at levels close to the proposed standard. In fact, we
20 believe that the science could justify an even lower
21 standard. Therefore, we strongly support the not-to-exceed
22 form of the standard.

23 This stipulation will ensure that the highest
24 allowable levels of PM2.5 throughout California will be
25 below the 98th percentile levels of PM2.5 that are

1 documented in most of these studies that show associations
2 between PM2.5 and mortality. The annual standard for PM2.5
3 alone cannot protect the public from the spikes in fine
4 particulate. And these are associated with mortality and
5 increases in admissions to hospitals for cardiovascular
6 causes and asthma, among other health problems.

7 We applaud the committee, as well as ARB and
8 OEHHA, for addressing this by proposing a 24-hour standard
9 for fine PM. Once again, we urge you to resist any pressure
10 to weaken the proposed standard, which is critical to the
11 public health throughout the state. Thank you.

12 CHAIRMAN KLEINMAN: Thank you very much.

13 Ken Kloc?

14 SPEAKER KLOC: Good afternoon. My name is Ken
15 Kloc. I am an environmental scientist and I work with the
16 Environmental Law and Justice Clinic at Golden Gate
17 University, and I'm also here today on behalf of Our
18 Children's Earth Foundation.

19 As you know, we have previously submitted comments
20 to the Air Resources Board and the OEHHA, in which we have
21 criticized the agencies for proposing standards that are
22 unlikely to be sufficiently protective of the public health.
23 In the past we have argued that the scientific data support
24 lower values for all the proposed PM standards.

25 In today's comment, I would like to address two

1 issues, one related specifically to the short-term PM2.5
2 standard, and another dealing with all of the standards.
3 First, regarding the PM2.5 standard, we are very pleased
4 that the agencies have decided that a 24-hour standard is
5 needed, and recognizing how difficult setting the standards
6 for PM are, given the epidemiologic data, we congratulate
7 you for doing that work; however, we cannot agree with the
8 method by which the agencies have chosen this proposed
9 standard. And we do not believe that 25 micrograms per
10 meter will provide an adequate margin of safety.

11 In developing the standard, agency staff have
12 attempted to discern an uncertainty threshold of sorts in
13 the 98th percentile values of PM2.5 concentrations observed
14 in short-term mortality studies. The problem with this
15 approach is that all of the lower concentration mortality
16 studies analyzed by the agencies have shown positive
17 effects, even if at somehow lower levels of confidence.

18 Two of the four lowest concentration cases, which
19 were derived from the study by Burnett and others, showed
20 positive associations and confidence levels that were
21 consistent with the high concentration studies that had been
22 looked at. Moreover, other epidemiological studies of
23 morbidity have showed serious health impacts at
24 concentrations lower than the 25-microgram-per-meter, cubed
25 value.

1 For example, a 2001 study on particulate matter
2 pollution and myocardial infarction by Peters, Dockery,
3 Mueller, and Mittleman looked for effects at five ranges of
4 PM2.5, with the lowest range at levels typical of
5 background. Each increment of either the 24-hour average or
6 the two-hour average concentration above the lowest study
7 level showed an increased risk of heart attack. Increased
8 risks with a confidence level greater of 95 percent were
9 observed for the 24-hour 2.5 concentration between
10 approximately 12 and 16 micrograms per meter, cubed, which
11 is significantly less than 25 micrograms per meter, cubed.

12 We believe that the results of the low
13 concentration mortality studies, taken together with
14 information from other studies such as Peters and others,
15 argues against an uncertainty threshold at or near 25 to 30
16 micrograms per meter, cubed; thus, the proposed PM2.5
17 standard may not be sufficiently health-protective.

18 Moving on to my second comment on PM standards in
19 general, I would like to call your attention to issues of
20 environmental justice that may arise in promulgating the PM
21 standards. In a recent letter to the Air Resources Board, a
22 coalition of 21 California-based community and environmental
23 organizations, including Our Children's Earth, pointed out
24 that, according to state law and our policy, the agency
25 staff should consider the possibility of environmental

1 injustice in their decision-making processes, and should
2 also attempt to alleviate any such injustice when developing
3 environmental regulations.

4 In its environmental justice policy document, the
5 Air Resources Board has stated that it is committed to
6 making the achievement of environmental justice an integral
7 part of its activities, and has defined environmental
8 justice as the fair treatment of people of all races,
9 cultures, and incomes, with respect to the development,
10 adoption, implementation, and enforcement of environmental
11 laws, regulations, and policies.

12 In addition, the California Code of Regulations
13 states that it is discriminatory to provide a person with an
14 aid, benefit, or service that is not as effective in
15 affording equal opportunity to reach the same level of
16 achievement as that provided to others. The code also makes
17 clear that in some cases, identical treatment may be
18 discriminatory. We believe that environmental justice
19 issues arise in the PM standard process as a result of two
20 circumstances.

21 The first circumstance is that the scientific data
22 show and the agencies admit that some portion of the
23 population will not be protected by the currently proposed
24 standards. Number two, numerous studies have indicated that
25 people of color and low-income communities are likely to be

1 disproportionately exposed to higher than average
2 concentrations of pollution, including particulate
3 pollution, since they tend to live closer to factories,
4 power plants, congested highways, and other pollution
5 sources.

6 In situations where a standard is set at a truly
7 safe level, disproportionate exposure may not be an issue;
8 however, for PM standards this is not the case. Therefore,
9 the agencies should consider adding a supplemental margin of
10 safety to their standards, in order to provide additional
11 benefits to communities experiencing environmental
12 injustice.

13 In conclusion, we again request that the Air
14 Resources Board and the Office of Environmental Health
15 Hazard Assessment revise the proposed standards in order to
16 increase their health protectiveness, and also, to decrease
17 current and future levels of environmental injustice.

18 Thank you.

19 CHAIRMAN KLEINMAN: Thank you. The next speaker
20 is Bonnie Holmes-Gen.

21 SPEAKER HOLMES-GEN: My name is Bonnie Holmes-Gen,
22 and I'm with the American Lung Association and the American
23 Lung Association of California. And we spoke at the last
24 meeting of your committee, and we are here today because we
25 are very pleased with the proposal that has come forward

1 from OEHHA and the Air Resources Board before your committee
2 to establish a 24-hour PM2.5 standard. And we believe this
3 proposal significantly strengthens the entire package of PM
4 standards that you have been reviewing, and it addresses
5 many of the concerns that we had raised earlier to your
6 committee.

7 We believe that both the proposed 24-hour PM2.5
8 standards and the annual 2.5 standard and the annual and
9 short-term PM10 standards are critical to protecting against
10 the full range of health effects reported in the scientific
11 literature. And it's important to protect against both
12 morbidity and the mortality effects.

13 We believe that staff has developed a strong
14 rationale for the proposed 24-hour standard, not to be
15 exceeded, and we strongly support the level and the form of
16 the proposed standard. Together with the Natural Resources
17 Defense Council and others, we want to caution you that the
18 standard should not be weakened or relaxed in any way. And
19 this is critical if it's going to protect public health with
20 an adequate margin of safety.

21 We want to highlight our support for the not-to-
22 be-exceeded form of the standard. We were extremely pleased
23 with this. We actually submitted a letter to your committee
24 in the interim, between the last meeting, asking you to
25 please consider a not-to-be-exceeded form. That's very

1 important to us, along with, of course, a very health-
2 protective standard. And we think that's most important
3 because the purpose of the 24-hour standard is, of course,
4 to protect against high daily concentrations, so we wouldn't
5 want to see any high excursions essentially excused in the
6 process of determining attainment.

7 We appreciate that the staff has proposed a
8 standard based solely on health concerns. And, as you know,
9 the California air quality standards by statute are to be
10 established based solely on health concerns. And since a
11 previous speaker had suggested that you consider what
12 regulatory levels might be most achievable or most
13 practical, I do want to stress that we are pleased that you
14 are following the letter of the law in looking at a proposal
15 that is based solely on health concerns, and we ask you to,
16 of course, continue to do that.

17 We support the proposal before you. You know, we
18 believe that the staff has addressed our concerns, and we
19 look forward to hearing the discussion. We also have to
20 comment that since, again, the impetus for reviewing the
21 ambient air quality standards and particulates specifically
22 is the Children's Environmental Health Protection Act, that
23 you could do -- that we would ask that you do everything
24 possible to highlight the protection that will be provided
25 to children by the health standard that's being proposed.

1 Thank you for the opportunity to present comments.

2 CHAIRMAN KLEINMAN: As I said, only five people
3 had signed up in advance. Were there any other individuals
4 from the public who wanted to make a comment? We could
5 afford a few more minutes.

6 If not, then I'd like to ask Bart Ostro, who has
7 prepared a summary of the written comments and the responses
8 to those written comments, and since we do have a little bit
9 of extra time, if there are oral comments that you feel that
10 you can address as well, we could probably work with those
11 also.

12 DR. OSTRO: Okay. Thank you, Dr. Kleinman.

13 I'm going to try to summarize the written comments
14 and our responses to them.

15 The first comment strongly supports the
16 establishment of a 24-hour PM2.5 standard, but believes the
17 current proposal is insufficiently protective of public
18 health and asks for additional margin of safety. That's
19 comments from the Asian Pacific Environmental Network and 20
20 other organizations.

21 And our response is based on the current evidence,
22 we believe that the proposal provides sufficient protection,
23 although we do state in the document that there is no
24 apparent risk-free level based on current evidence. In
25 addition, we believe that the issue of environmental justice

1 should be addressed more in the implementation of the
2 standards and the control strategies, rather than in the
3 actual setting of the standards.

4 The group also had a comment that they believe
5 that both the annual -- the 24-hour PM10 and the annual
6 average PM2.5 should be lowered, those standards should be
7 lowered, and our response was that these issues were
8 addressed at the last scientific review meeting by AQAC, and
9 that the committee as a whole believed that our
10 recommendations were supported by the available evidence.

11 The next comment was, if I can summarize comments
12 by Ford Motor Company and the Alliance of Automobile
13 Manufacturers, the comment said asserting the lack of a
14 threshold is premature and is problematic because of
15 measurement error and confounding. We have several
16 responses to this comment. As we indicated last time at the
17 meeting, that the exploration of possible thresholds in
18 several large multi-city studies, as well as single-city
19 studies, using a variety of statistical approaches showed no
20 evidence for a threshold. There are a few exceptions to
21 those, but the preponderance of evidence is supporting, is
22 indicating no evidence for a threshold.

23 Statistical tests have indicated that linear or
24 near-linear non-threshold models provide the best fit of the
25 data. An additional bit of evidence for effects at lower

1 levels and potentially precluding a threshold is the fact
2 that, as we've reported, there are several studies at very
3 low concentrations of PM2.5 and PM10 that do find effects,
4 but as we've indicated, the uncertainties in terms of the
5 confidence interval around these estimates are larger, and
6 Dr. Lipsett has indicated several reasons why these
7 confidence intervals might be larger at these lower levels.
8 But there are certainly studies at fairly low levels of
9 concentrations.

10 However, we do want to add that because of issues
11 that the reviewers and commenters -- that is, because of
12 exposure, mismeasurement -- one cannot categorically rule
13 out the possibility of a threshold. But the current
14 evidence does not really support any kind of threshold at
15 this time.

16 Besides the Chalk study that was referred to in
17 the comments, both written and oral, there is also evidence
18 from simulation studies done by Cakmat et al., using some
19 Canadian data. And basically, the findings of both of those
20 studies are consistent and indicate that unless the
21 measurement error is extreme -- that is, the difference
22 between the real measurements and actual exposures have
23 correlations below, say, .4 -- that for most of the
24 concentrations that we're talking about, the likelihood of
25 actually finding a threshold given one exists was about 80

1 percent, 75 to 80 percent. So it's extremely likely that
2 with even moderate exposure misclassification that you would
3 still find a threshold, if one existed in these studies, and
4 the preponderance of the evidence has indicated that one
5 does not exist.

6 The next comment by Ford and the AAM, the
7 automobile manufacturers, is that the proposed 24-hour
8 standard does not acknowledge the lack of controlled
9 experiments demonstrating effects at or around the level of
10 a standard, and that only controlled studies can credibly
11 establish a causal relationship between PM exposure and
12 health end points. And our response is that we disagree
13 that only controlled studies are sufficient for causal
14 inference, especially for the study clearly of PM and
15 mortality, that most etiologic inferences in medicine are
16 based on epidemiologic studies, not necessarily on
17 controlled exposures.

18 That using the generally accepted guidelines for
19 causal inference that we've detailed in the document, the
20 relationships between particulate matter and adverse health
21 impacts are fully discussed and they're met in our section
22 7.9, and finally, we agree that the risk estimates, the
23 specific quantitative risk estimates may be sensitive to the
24 city or region under study, to the model specification, how
25 the weather factors are controlled for, the amount of

1 measurement error, and the inclusion of correlated co-
2 pollutants.

3 So the actual risk estimate per microgram will
4 change or can change, depending upon some of these factors;
5 however, we feel that this aspect does not invalidate the
6 causal relationship between ambient PM and the adverse
7 health outcomes that we discussed in detail at the previous
8 meeting.

9 The next comment that we generalized was from
10 Ford, the engine manufacturers and the automobile
11 manufacturers. And the comment is that the proposal ignores
12 the nature of PM as a mixture, with constituents of varying
13 toxicity, that this may lead of control of the wrong
14 components with few health benefits. And our response is
15 that there is certainly an ongoing debate over whether the
16 toxicity is more related to particle size, mass, number and
17 specific constituents, and that more research is clearly
18 necessary and we'll be indicating that in the document.

19 Certainly, new information will be incorporated
20 into the policies, control strategies and standards over
21 time, as that information becomes available. There was some
22 indication in the written comments that there was a concern
23 that the Air Resources Board might be ultimately regulating
24 inert and non-toxic particles. And again, if information
25 becomes available that certain subspecies are relatively

1 benign, I'm sure that will be reflected in the control
2 strategies further down the line; however, again based on
3 the evidence that's out there to date in the scientific
4 literature, we thought our treatment of the relative
5 toxicity was consistent with that literature.

6 It's also generally accepted among researchers
7 that combustion-related particles appear to be more toxic,
8 and the relative toxicity again will come into play when the
9 districts, in coordination with the Air Resources Board,
10 develop prioritizations for control strategies.

11 Next is comments by the engine manufacturers
12 association, that there is insufficient evidence to develop
13 a 24-hour standard at this time, and that we should revert
14 to our original conclusions about this issue. Our response
15 is that the 24-hour standard proposal was based on guidance
16 from the Air Quality Advisory Committee, whose members
17 unanimously indicated that the evidence warranted such a
18 standard.

19 And that there are several lines of evidence
20 underlying such rationale, as Dr. Lipsett indicated earlier.
21 First, that fine particles do deposit throughout the lung
22 and are retained in large quantities; second, that fine
23 particles have been linked in controlled studies with lung
24 inflammation, although at higher levels. There is evidence
25 that the fine particles easily penetrate into residences,

1 and finally, that there are many now epidemiologic studies
2 indicating associations between PM2.5 and daily morbidity
3 and mortality, as well as long-term exposures relating to
4 mortality.

5 Next point, the comment summarized here is by the
6 engine manufacturers, that our table 7(a) suggests only weak
7 and insignificant effects of PM at the 98th percentile
8 concentrations lower than 42, and that annual means less
9 than 17, and that this suggests that the proposed standard
10 or short-term standard is too stringent. So our response is
11 that all the point estimates for the studies are greater
12 than zero, in terms of the percent change expected in
13 mortality per ten micrograms, all show positive
14 associations.

15 If you want to use statistical significance,
16 you'll find significant effects in both Vancouver and the
17 Phoenix study where the 98th percentile are 30 and 32,
18 respectively, and there is no principled rationale to
19 dismiss the results of those studies, as well as the general
20 sense of all of the other studies of a positive association.
21 So although, as we've indicated, the uncertainties are
22 greater at these lower levels, we feel that there is
23 sufficient evidence to move on the standard.

24 The next comment is by the Alliance of Automobile
25 Manufacturers that the uncertainties in the data underlying

1 the proposed standard should be more clearly indicated. Our
2 response is that some of the uncertainties in the
3 epidemiologic data are described throughout the document and
4 in section 7.10.5; however, we will be adding some
5 additional documentation in the report, and provide a better
6 description I think of some of these studies to indicate
7 some of the uncertainties in the studies.

8 So we don't necessarily disagree with this
9 comment. There are uncertainties in the studies, and it's
10 certainly difficult to characterize a very detailed study
11 with one or two relative risk estimates. So we're going to
12 try to add some more documentation to the study about the
13 ranges of the relative risks and the confounders and so on,
14 how some of these factors are treated in these studies and
15 what the results are.

16 A comment by the American Lung Association that
17 they strongly support the proposed 24-hour standard, so our
18 response is -- none required. And that does our summary of
19 the written comments, and I'm open to any additional
20 questions that the members might have.

21 CHAIRMAN KLEINMAN: Bart, in the report you did
22 address to some extent the issue of single-pollutant models
23 versus multiple-pollutant models, but that was raised in
24 some of the written comments and the oral comment given
25 today.

1 Could you perhaps review that issue for us again,
2 in terms of how the single- and multiple-pollutant models
3 were used?

4 DR. OSTRO: Yeah. In our tables we have basically
5 provided evidence of results from single-pollutant models.
6 And we feel that the best way to know what the effects are
7 of other pollutants or whether the pollutants are
8 confounding PM is by selection of cities or regions that
9 have different associations with particles. For example,
10 conducting studies where particles and SO2 are highly
11 correlated, like in the old London data and in parts of
12 Europe. And then conducting a similar study, say, in
13 California which has very, very low SO2 levels.

14 And by picking cities very carefully, we think
15 you're best able to separate out the effects of one
16 pollutant versus another; likewise, with ozone. Some areas
17 have very highly correlated values of PM2.5 and ozone, such
18 as the northeast and some of the Canadian studies, the
19 Montreal and Toronto studies, but in other areas, when
20 you're looking at daily mortality or morbidity studies, you
21 can actually pick times where the correlation between PM2.5
22 and ozone are relatively low.

23 And when you repeat those types of studies with
24 highly correlated SO2s and ozones and other pollutants, and
25 low correlate it and still get the same effect, we think

1 that's the strongest evidence for effects for particulate
2 matter. As I mentioned in the last AQAC meeting, when you
3 start throwing lots of co-varying highly collinear
4 pollutants into a model, you're guaranteeing basically that
5 the standard error of the particle coefficient will increase,
6 which means a lower statistical significance. It's not a
7 surprise when you enter a highly collinear variable that the
8 statistical significance of the coefficient will drop.

9 Another aspect of the problem is that the
10 coefficients will become highly variable, they will swing
11 widely which is another characteristic of multi-collinearity
12 in these models. So there is certainly a tradeoff. When
13 you don't include other variables, you can get omitted
14 variable bias, and if something like CO or NO2 or ozone were
15 causally related to these factors, you are biasing the
16 coefficients by not including them.

17 But, in general, we thought -- we believe, and
18 many agree with us, that you're really not adding much
19 information by adding collinear pollutants into the model.
20 So in the document we try to discuss this issue as I have
21 and try to point out the best ways to go about analyzing the
22 effects of other pollutants and what the implications are of
23 having models that have lots of collinear pollutants in
24 them.

25 So I think that's how we've pretty much chosen to

1 deal with that issue.

2 CHAIRMAN KLEINMAN: Thank you.

3 Are there any other questions? Yes, Dr. Cropp.

4 DR. CROPP: I think one issue or one fact that you
5 mentioned that I think needs to be discussed a little more,
6 and that is that retention of particles is a very important
7 aspect of our considerations in children, because of their
8 relatively higher ventilation per lung size, and also their
9 greater spontaneous activity; therefore, their average daily
10 ventilation compared to adults.

11 I think that retention of particles is going to be
12 much greater than it is in adults, and, therefore, even at
13 low concentrations the risk of being adversely affected is
14 also greater. And I think that should be included in the
15 discussion or the rationale of why it is important to lower
16 the 24-hour threshold to the level that has been proposed.

17 DR. OSTRO: There is a section in the main
18 document that does refer to deposition clearance and
19 dosimetry which has been revised somewhat in relation to
20 some of the public comments received and comments from the
21 committee at the last meeting, and that will be in the final
22 document as it comes out.

23 But you're suggesting that something like this be
24 added as well to the rationale part, in addition to the
25 section that's explicitly devoted to issues related to

1 deposition and clearance?

2 DR. CROPP: My suggestion is that it be added to
3 the rationale because it indicates that there is a greater
4 risk for children, as far as their respiratory morbidity is
5 concerned. Even at the same standard, I don't know whether
6 I expressed myself clearly, but the standard of 25, for
7 instance, is still more risky for children than it is for
8 adults, because they retain more particles per day than the
9 adult will, as far as the surface of their respiratory
10 system is concerned, the internal surface of their
11 respiratory system is concerned.

12 And I wonder whether other members of the panel,
13 like Dr. Sheppard or Dr. Gong, would agree with that.

14 DR. GONG: I think I would support what Dr. Cropp
15 has said. I was also thinking in terms of exposure,
16 particulate exposure to heat levels. I don't know if the
17 data says this, but I assume that children probably spend
18 more time outside than adults, in general, according to ARB
19 data. So they're also perhaps more likely to be exposed to
20 the acute peaks that this particular 24-hour standard is
21 dealing with.

22 So, in that regard, I would support what you say
23 about dosimetry and retention as well.

24 DR. CROPP: Well, it's also my understanding that
25 the smaller the particle gets, the more indoor penetration

1 there is of these particles. And even if children are
2 living in so-called locked-up situations, as they often do
3 in large cities because of safety issues, they still are
4 exposed.

5 DR. GONG: And the exposure is still at a peak
6 sometimes, yeah.

7 DR. LIPSETT: I'm aware of a number of modeling
8 studies and a couple of exposure studies that suggest that
9 children will have a higher rate of particle deposition, and
10 I'm not actually aware of studies looking at retention, per
11 se, in children, that they're going to retain particles
12 differentially compared to adults, other than based on these
13 considerations of deposition. Is there some literature on
14 this that you're familiar with?

15 DR. SHERMAN: The only literature that exists
16 doesn't have to do with air pollution particles, because
17 they would be difficult to label and track, but there is
18 data on bacterial particles actually produced by us many
19 years ago that were less than four microns, which were
20 cleared more slowly and there was an age-related increase in
21 mucociliary clearance.

22 Part of that is due to the fact that the actual
23 cilia are underdeveloped the younger you go down, so
24 prematures have fewer cilia than term infants, and there is
25 a gradual maturation of that over the first few months. So

1 there is definite evidence that at least bacterial particles
2 are going to be retained, more slowly cleared, and that
3 there is an age-related improvement in mucociliary
4 clearance. So I would assume that whether it's bacteria or
5 some other particle of less than four microns that it's
6 going to be more slowly cleared.

7 DR. CROPP: And there is also some evidence that's
8 not necessarily in children but whatever is deposited a
9 fraction of that is incorporated and absorbed and is
10 retained in the lung. And I'm not aware of what that
11 fraction is, but there is evidence that some of the
12 deposited material is engulfed by macrophages and so on, and
13 is then carried into the circulation. And I think some of
14 the cardiovascular effects that have been described in
15 adults are based in part on the degree of absorption of some
16 of the deposited particles, if I interpret that data
17 correctly.

18 CHAIRMAN KLEINMAN: If there are no other
19 questions, Bart?

20 DR. OSTRO: One area I forgot to mention about the
21 comments are OEHHA's response to comments was based on
22 health questions. There were several comments that came up
23 regarding issues of control strategies and monitoring. I
24 think three general issues: one was on background
25 considerations; a second was on the controlling standard,

1 annual versus a 24-hour; and a third was the not-to-be-
2 exceeded issue.

3 So I'm going to hand it over to Dr. Bode to
4 address those issues.

5 CHIEF BODE: Thank you. Bart has been so gracious
6 to let me answer these, and he's -- Right, to kind of
7 summarize these comments, one is the PM2.5 24-hour standard
8 is too stringent, that it basically becomes the controlling
9 standard and, by doing so, it forces the annual average
10 concentrations down to backgrounds.

11 And first off, I have to agree. The proposal we
12 have is a stringent standard. But it's a health-based
13 standard, and that's kind of what separates California law
14 probably from what US EPA follows too. Our standards are
15 meant to be health-based. The current relationships we see,
16 we have done a preliminary study of peak-to-mean ratios that
17 do show about a 2.5 to 3 ratio of these peaks to means,
18 which mean a 25 microgram standard would be somewhere down
19 to about eight to ten micrograms in the annual average.

20 Background we're still looking at as being 4 to 5.
21 But a better question is that as these peaks are reduced
22 over time that this ratio really is based on pretty limited
23 data we have on PM2.5 now that, as we do work on the peaks,
24 that what happens to these ratios? Do they basically stay
25 the same over time? Or basically the relationships are

1 based on the -- you know, based on the ambient
2 concentrations to the emission profiles, do those things
3 compress over time too?

4 So we basically see a compression of these. And
5 so, frankly, the 25 does get pretty close to the 12, but
6 what we've basically seen, that the two standards get to be
7 pretty equivalent over time.

8 And that's something I think we won't know for a
9 while, until we start seeing the effects, some of the
10 control methodologies that will be proposed in the future,
11 which really brings me to the question of the whole process
12 in California, that we do separate the standard setting from
13 the control process. That the standards are not set with
14 feasibility of attainment in mind, but what we think is a
15 health-based standard to protect public health.

16 And that is our main emphasis, that the
17 feasibility of controls come in during the second phase of
18 this process, and that is when we -- with other parts of the
19 Air Resources Board, not the Research Division or OEHHA,
20 work on proposing controls, regulatory ideas for controlling
21 particulate matter. And that's when feasibility will come
22 into question.

23 And I can tell you that the Air Resources Board
24 does not intend to regulate down to background levels of PM,
25 that if we go and we look at the feasibility and they aren't

1 feasible, that's something that will be considered during
2 the control process itself. But we need to set standards
3 that we think are health-based, so that the people, the
4 public health is protected.

5 The other thing that Bart had brought up was this
6 never-to-be-exceeded form of the standard and that, you
7 know, some of the comments are that it sets an unattainable
8 goal. And this is some of the confusion actually that we
9 probably need to clear up in the staff report, that in
10 California the actual standard setting and the form of the
11 standard are actually in two separate processes, that there
12 is a separate area designation, attainment designation
13 process that's done, separate from the setting of the
14 standards.

15 It gets back again to the standard setting being
16 based on the health effects information, the health-based
17 standard. That's the information that's used to set the
18 standard so we can basically tell the public what we think
19 is clean air and what isn't. The actual area designation
20 and how you determine whether an area has met the standard
21 or not is dealt with in a separate process. It's a separate
22 process in the Health and Safety Code, Health and Safety
23 Code 396070 that basically allows the board, through a
24 separate process, to set up separate criteria.

25 This also allows us to take into consideration

1 uncontrollable sources, episodic events such as forest
2 fires, windstorms, things like that that aren't included in
3 the standard attainment criteria themselves, but still does
4 not change the level of standard. So I think both of these
5 are taken into consideration. I think the idea, the form of
6 the standard being separate from the standard setting
7 process is probably something we can clear up in the staff
8 report too so these are more illuminated.

9 CHAIRMAN KLEINMAN: Thank you. Any other comments
10 from the committee?

11 If not, we are scheduled for a 15-minute break.
12 We're running a little ahead of our schedule and I think
13 that's good. And so I'd like to break now for 15 minutes,
14 and we'll get back at about ten of 3:00.

15 (Thereupon, a recess was
16 held off the record.)

17 CHAIRMAN KLEINMAN: I'd like to first of all take
18 the opportunity to thank the ARB staff and the OEHHA staff,
19 who worked extremely hard to meet the requirements and the
20 demands of the committee and put together a standard that
21 was responsive to the requests that were made.

22 I think that in doing so, they had to balance a
23 number of competing issues. For example, the issue of
24 making the short-term standard consistent with the annual
25 standard. That issue was addressed, and this had to be

1 balanced with a need to provide a reasonable margin of
2 safety, which is part of the rules under which the standard
3 setting process is designed. And I believe the committee by
4 and large is extremely pleased with the outcome.

5 During the process, we had a subgroup of this
6 committee involved in a telephone conversation with Richard
7 Bode, Michael Lipsett and Bart Ostro, as part of the
8 development of the proposed 24-hour standard, and that
9 subgroup consisted of Dr. Tager, Dr. Sheppard, Dr. Balmes,
10 who couldn't be here today, and myself. And so I'd first
11 like to ask members of the subgroup if they would like to
12 make any additional comments regarding the 24-hour standard
13 and scientific basis and the recommendation.

14 I'll start with Dr. Tager.

15 DR. TAGER: I have no further comment. I thought
16 they did a good job of articulating what they did and the
17 rationale for doing it, and expressed appropriately the
18 uncertainties involved in trying to do this under the
19 assumption of no threshold. So I don't have any specific
20 comments, I was pleased with what they wrote.

21 CHAIRMAN KLEINMAN: Dr. Sheppard?

22 DR. SHEPPARD: I fully agree with what Ira said.
23 I wasn't on the conference call because I was unavailable
24 for the call, but I think the document that we were sent,
25 the proposed standard and the rationale make a lot of sense

1 and accurately reflect the input we gave last time.

2 CHAIRMAN KLEINMAN: Okay. I was particularly
3 pleased with the tack of putting the standard in the not-to-
4 exceed form. I think that was an important issue. I think
5 it does add to the margin of safety. I did want to amplify,
6 and Dr. Sioutas had pointed out as well, in the presentation
7 Dr. Ostro made earlier he mentioned the importance of lung
8 inflammation and the fact that there were short-term data
9 that indicated that there were impacts on lung inflammation
10 as well as mortality.

11 In addition, there were also a fair number of data
12 regarding cardiovascular effects and cardiovascular
13 morbidity that may be extremely important in the final
14 analysis as well. And I think, from my standpoint, the
15 rationale for the standard was well put forth and adequately
16 documented in the proposed standard.

17 I'd like to open it up to the rest of the
18 committee, if there are any additional comments regarding
19 the presentation made today, the oral comments or the
20 standard as we've had it to review, if there are any
21 additional comments that the committee would like to make at
22 this time.

23 We'll just go around the table, starting with
24 Dr. Sherwin.

25 DR. SHERWIN: Well, in the future I would make a

1 recommendation that we go into the rationale in a little
2 more depth. There were a lot of points raised about
3 threshold, deposition, clearance, injury, and I think they
4 are a lot of the points I was going to get into but I think
5 that it belongs at a different time. But there definitely
6 is a need to do more about what is the basic health problem.

7 CHAIRMAN KLEINMAN: Dr. Cropp?

8 DR. CROPP: I am very pleased with the draft
9 proposal that you folks have prepared, and I think that I'd
10 just like to reemphasize that this document is one that sets
11 standards. It's not a document that controls pollutants,
12 but it is a document that determines or sets standards where
13 they should be.

14 I think that is our job here in this committee to
15 set where -- advise where the standards should be, based on
16 what is achievable and also what is desirable, and what is
17 known about the health effects or the pathological effects
18 of air pollution. And, consequently, I think that these are
19 goals to be achieved, hopefully soon, and we are not in the
20 business of the implementation of these standards.

21 CHAIRMAN KLEINMAN: Dr. Sherman?

22 DR. SHERMAN: I am in full agreement with this
23 standard. I took some of the domains or the cities listed,
24 and tried to match the topography and climatic conditions to
25 California, and then do a real statistical analysis and came

1 within one microgram per cubic millimeter of what was the
2 standard that was set. So it was a smaller number of
3 cities, but I thought better and more representative of
4 California.

5 The other comments that I had already made to
6 Mr. Bode would have to do with future directions for
7 research, particularly on infants under a year of age and
8 the diad of the pregnant mother and the fetus, and what
9 adverse effects that will have. And whether these new
10 standards, in fact, will improve their health, particularly
11 in high-risk areas of California.

12 CHAIRMAN KLEINMAN: Dr. Gong?

13 DR. GONG: I just have several short comments.
14 First of all, I'm very pleased that we have two able and
15 well-qualified pediatricians on this committee. Actually,
16 when I came here today that was certainly my area of my most
17 uncertainty, if you want to call it that. So it's
18 reassuring to hear from both of you on the opposite table
19 here supporting the 24-hour standard, so thank you.

20 I'd also like to comment that there will be --
21 well, in the near future there will probably be more data
22 indicating human data showing inflammation and other types
23 of systemic effects in PM-exposed volunteers. And I think
24 that can be factored in at the next AQAC meeting on this
25 particular topic.

1 I'm also signing up volunteers for controlled
2 studies. Thank you.

3 (Laughter.)

4 DR. SIOUTAS: I also want to voice my support to
5 the committee's proposition for a new 24-hour standard, and
6 I think the office of OEHHA and ARB have done a very, very
7 fine job in putting this draft document together. They've
8 done whatever the committee that I had a singular privilege
9 to serve upon asked them to do.

10 There is no question that as our research
11 progresses we're going to have more information about
12 possibly chemical constituents within the particulate matter
13 that may be more toxic than others; however, as we all know,
14 regulation is based on what is available current evidence.
15 And in that respect, I think the office of OEHHA and
16 Drs. Ostro and Lipsett, these are congratulations for
17 putting together a report of that caliber.

18 As Dr. Kleinman mentioned, the literature of, so
19 to speak, control studies on the particulate pollutants is
20 increasing. And as it is increasing, it keeps bringing
21 evidence that there are cardiac and respiratory inflammatory
22 effects at concentrations that are by no means unheard of,
23 you know, concentrations on the order that we often see in
24 24 hours in Los Angeles.

25 We also have now, through our particle center in

1 Los Angeles, both in vitro as well as in vivo evidence at
2 environmentally relevant concentrations that link
3 particulate matter to cardiac or inflammatory effects of
4 oxidative stress generation, and apropos of the comment made
5 by the gentleman who is a representative of the automotive
6 industry, what I have to say is that the evidence the
7 regenerate is, in fact, if anything damaging to the
8 automotive industry. If we talk about the uncertainties on
9 particulate matter, one thing that is certain is that what
10 is emitted from automotive vehicles is, in fact, of the most
11 toxic groups of constituents that we find.

12 So, in general, I'm in full support of the new
13 standard, not to be exceeded, and I want to commend again
14 the board for its very fine job.

15 DR. SHERWIN: Mike, when I made my comment about
16 the need for more basic information, I was implying that
17 with that information it would show that the recommendations
18 made by the committee, by OEHHA were very conservative. And
19 that we'll get far more support with special attention to
20 the real problem. So it's a need to show that really, we
21 have just begun to get at the real part of human health
22 injury.

23 CHAIRMAN KLEINMAN: Thank you.

24 Are there any other comments? If not, do OEHHA or
25 ARB want to make any responses to the verbal comments of the

1 committee? I don't think -- No, okay.

2 In that case, again I'd like to thank the staff of
3 both agencies for doing a tremendous job. They've done an
4 awful lot of work in a relatively short period of time. I
5 know it was quite stressful and labor-intensive, and the
6 committee very much appreciates the effort.

7 We feel that the recommendations that have come
8 forth are going to protect the health of the residents of
9 California and we're very pleased with that. And on that
10 note, I'd like to adjourn the meeting.

11 CHIEF BODE: Could I add one more thing too?

12 CHAIRMAN KLEINMAN: Yes.

13 CHIEF BODE: Just to keep in mind that the
14 committee, too, what we need also is the findings from the
15 committee that I know I've talked to you about,
16 Dr. Kleinman, and those will be included in the final staff
17 report, your comments. So those members of the committee,
18 if you could get your final comments to Dr. Kleinman as soon
19 as you could, just because we have a very tight time frame
20 here, and I'd like to actually thank all the committee
21 members for all the time you've invested into this, and it's
22 been very helpful to us at both ARB and OEHHA, but I think
23 also the public citizens of the state of California have
24 your expertise weighing on this subject.

25 So I want to thank you very much, and I want to

1 thank the public for coming as well. Thank you.

2 CHAIRMAN KLEINMAN: Thank you.

3 (Thereupon, the hearing was

4 adjourned at 3:13 p.m.)

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CERTIFICATE OF REPORTER

I, VALORIE PHILLIPS, an Electronic Reporter, do hereby certify that I am a disinterested person herein; that I recorded the foregoing Air Resources Board public hearing; that it was thereafter transcribed into typewriting.

I further certify that I am not of counsel or attorney for any of the parties to said workshop, nor in any way interested in outcome of said hearing.

IN WITNESS WHEREOF, I have hereunto set my hand this 22nd day of April, 2002.

VALORIE PHILLIPS

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